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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,266	09/22/2000	Keith E. Robison	35800/204489	9505

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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	23

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/668,266	ROBISION ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21,29,30,32-35 and 44-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,21,29,30,32-35 and 44-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21, 29-30, 32-35, and 47-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification has been found to provide an adequate written description for phosphodiesterases that comprise the amino acid sequence set forth in SEQ ID NO: 1 and SEQ ID NO:3 and that encoded by the cDNA insert contained in ATCC patent Deposit No. PTA-1644. The specification has not, however, been found to provide an adequate written description neither for those phosphodiesterases that have any heterologous sequence attached thereto, nor for any of the myriad variants of said phosphodiesterases. While agreement is reached in that applicant, in an attempt to satisfy the written description requirement, does not need to disclose each and every species encompassed by the genera, the specification does need to provide an adequate written description of the claimed invention such that one would be readily capable of recognizing just what the members of the species are and to reasonably suggest that applicant, at the time of filing, was in possession of the invention. While the presentation of species that represent the degree of variance encompassed is one possibility, the specification can also satisfy the written description by a

showing of those residues that are required so to preserve the requisite phosphodiesterases activity. In the case of 29 and claims that depend therefrom, the polypeptide is claimed not in terms of the amino acid residue sequence, but in terms of the nucleotide sequence that is used to encoded said polypeptide. The specification has not been found to teach in sufficient detail jut which regions of the nucleotide sequence must be preserved, which residues can be substituted, and just which replacement residues can be employed so to preserve the requisite phosphodiesterases activity of the encoded protein.

3. In the case of claim 34 and 35, the polypeptide is again not defined in terms of the amino acid sequence but in terms of hybridization conditions. Such conditions, which applicant has labeled as "stringent," do not require that the isolated nucleic acid be full length or that it even be in proper reading frame. In short, the claim fairly encompasses any and all nucleic acids that will hybridize under the specified conditions. While one could argue that applicant is seeking only those sequences that encode a polypeptide that has phosphodiesterases activity, neither the claims nor the specification provides an adequate written of these sequences such that one would be able to readily identify which nucleic acid sequence is fairly encompassed by the claim as opposed he those that may encode the polypeptide but for some reason lack the requisite phosphodiesterases activity.

In the case of claim 53 and claims that depend therefrom, the claims require that one use a polypeptide that comprises "at least 50 contiguous amino acids of the amino acid sequence set forth in SEQ ID NO:1" or of SEQ ID NO:3, or that which is encoded by PTA-1644. SEQ ID NO:1 is represented as being 502 amino acids in length; SEQ ID NO:3 is 320 amino acids in length. Looking at SEQ ID NO:1 and then just at polypeptides that are from 50 to 60 contiguous

amino acid residues in length, one finds that there are over 4,900 different peptides to evaluate. A review of the disclosure fails to provide an adequate written description of the polypeptides that are 50-60 amino acid s in length, much less those polypeptides that are 60-501 amino acids in length. The problem is only compounded when one looks to SEQ ID NO:3 and to PTA-1644. While one may argue that it would be obvious to one of skill in the art to readily determine just which polypeptide work and which do not, such an argument is not persuasive towards withdrawal of a rejection based on an insufficient written description. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

4. In the case of claim 57 and claims that depend therefrom, the claims fairly encompass any and all possibly fragments of SEQ ID NO:1, SEQ ID NO: 3, and the cDNA insert of plasmid deposited with the ATCC as PTA-1644 that encode a polypeptide that has phosphodiesterases activity. A review of the specification fails to find an adequate written description of just which fragments or regions of SEQ ID NO:1, SEQ ID NO:3 or of the amino acid sequence encoded by PTA-1644 are required so to ensure that the resultant polypeptide does have in fact the requisite phosphodiesterase activity.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 19, 21, 29, 30, 32-35, 44, 46-49, 51-55, and 57-59 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sasaki et al. (Biochemical and Biophysical Research Communications 271, 575-583, 2000).

10. For purposes of examination, the phase "the amino acid sequence" in claim 19 has been interpreted as encompassing both the full or complete length as well as less than full or complete length of the recited amino acid sequences. In the case of claim 29 and claims that depend therefrom, the phrase "sequence identity" has been interpreted broadly so as to encompass any values ascribed to the variables in any algorithm (e.g., Matrix, k-tuple, Mismatch Penalty, Joining Penalty, Randomization Group Length, Cutoff Score, Gap Penalty, Gap Size Penalty, Window Size or the length of the subject nucleotide sequence) used to determine "sequence identify."

11. Sasaki et al., disclose a phosphodiesterase. Page 578, illustration "A" discloses the amino acid of their phosphodiesterase that, starting at amino acid 28, matches perfectly the remaining amino acids of SQ ID NO:1. It is also noted that this same figure also teaches explicitly the nucleotide sequence that encodes this polypeptide and that this polypeptide is shown with additional amino acid residues. At least one of these residues is considered to be found in heterologous proteins.

12. In the event that the disclosure of Sasaki et al., does not anticipate the claimed invention, the amino acid and corresponding amino acid sequences would have been obvious to one of ordinary skill in the art at the time that the invention was made in view of the detailed guidance provided.

Conclusion

13. Rejections that appeared in the prior Office action and not repeated hereinabove, have been withdrawn.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
September 14, 2002